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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

7590 06/29/2004

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,20 and 22-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,20 and 22-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 6/22/04
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Amendment filed 03/15/04.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: fluoxetine, fluovoxamine, paroxetine, and sertraline.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 24 and 47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Eudragit® being a rate release coating polymer at 4%, 6%, 8%, 10.0%, 12% and 15%, does not reasonably provide enablement for any rate-controlling polymer at any percent amount. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. It appears from the specification at page 24, tables 4 and 19, that only Eudragit® in an amount of 4%, 6%, 8%, 10.0%, 12% or 15% will exhibit the release rates claimed in claims 23, 24 and 28-30.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman EP 0 797 991 A1.

Sherman teaches an extended release composition comprising an antidepressant in a form of coated beads or spheroids (page 3, lines 13-30). The coated beads filled into hard gelatin capsules having a release profile as showed in table 1 (pages 3-4). Sherman also teaches that the dosage form is a 24 hours extended release formulation (abstract).

It is noted that the Sherman does not expressly teach the release profiles. However, Sherman teaches a controlled release composition having the release profile of claim 25 (see table 1). It is the position of the examiner that the composition of Sherman would exhibit the release profile of claim 24, because Sherman teaches an extended release composition comprising active beads coated with film coating polymer (rate controlling polymer).

Claims 24 and 45-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al. US 5,958,458.

Norling teaches a pharmaceutical multiparticulate formulation in the form of coated cores (abstract). The core is in the form of pellets, comprising active agent and excipient (columns 2, lines 33-42; and column 13, lines 29-67). The active agent including antidepressants (column 6, lines 35-40). The coated multiparticulate is

formulated into oral solid dosage form including tablet, capsule, powder or granule suitable to release active agent during a 24 hours period (column 13, lines 20-36). Suitable coating polymers including ethyl cellulose, Eudragit® E, Eudragit® RS or RL, polyvinyl acetate phthalate (columns 9-10).

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly, it is the position of the examiner that the release profile is inherent because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 20 and 22-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman EP 0 797 991 A1, in view of Zentner et al. US 4,851,228.

Sherman is relied upon for the reason stated above. Sherman does not teach the specific antidepressant drug.

Zentner teaches multiparticulate controlled delivery system comprising active core coated with rate controlling water insoluble wall (column 2, lines 57 through column 3, lines 1-10; column 10, lines 59 through column 11, lines 1-51). The active agent in the core including antidepressant, *e.g.,* fluvoxamine (column 14, lines 4-13). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the extended release formulation of Sherman using fluvoxamine as an antidepressant in view of the teaching of Zentner, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

It is noted that the Sherman does not expressly teach the release profiles. However, since applicants' claims lack the require structures to exhibit the claimed release profile, the burden is shifted to applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 1-5, 20 and 22-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman EP 0 797 991 A1, in view of Van Balken et al. US 6,183,780.

Sherman is relied upon for the reasons stated above. Sherman does not teach the specific antidepressant drug, such as fluvoxamine as claimed in claim 22.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, *e.g.,* fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the extended release formulation of Sherman using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

It is noted that the Sherman does not expressly teach the release profiles. However, since applicants' claims lack the require structures to exhibit the claimed release profile, the burden is shifted to applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 1-5, 20 and 22-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780.

Norling is relied upon for the reason stated above. Norling is silent as to the specific teaching of antidepressant drug, such as fluvoxamine.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, *e.g.,* fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify pharmaceutical multi-particulate formulation of Norling using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

It is noted that the Norling does not expressly teach the release profiles. However, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or

obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Accordingly, it is the position of the examiner that the release profile is inherent because Norling teaches the use of the same rate control release polymer, *e.g.*, Eudragit® E, Eudragit® RS or RL.

Response to Arguments

Applicant's arguments filed 01/23/03 have been fully considered but they are not persuasive.

Applicant argues that Zentner teaches fluvoxamine in a lengthy list of drugs. None of the examples discloses the use of fluvoxamine or any other SSRI. However, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994). Furthermore, Zentner is relied upon solely for the teaching of fluvoxamine is a well-known antidepressant. Accordingly, the 103 (a) rejection over Sherman in view of Zentner et al. is maintained.

Applicant argues that neither Sherman nor Van Balkan discloses a formulation which has specified release properties, as set forth in applicants' claims. accordingly, the combined disclosures of these two references would not lead to applicants' formulation. Contrary to the applicant's argument, the burden is shifted to applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on inherency'

under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al. and Zemlan et al. are cited as being of interest for the teaching of an enteric pellet comprising a core containing fluoxetine.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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